

Application No. PCT/US03/17347
Amendment dated December 2, 2004
Preliminary Amendment

Amendments to the Claims:

This listing of claims will replace all prior versions, and listings, of claims in the application:

Listing of Claims:

1. (originally presented) A pharmaceutical composition comprising:
 - i) a safe and therapeutically effective amount of (1*S*, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol or a pharmaceutically acceptable derivative thereof;
 - ii) a safe and therapeutically effective amount of (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof; and
 - iii) a pharmaceutically acceptable highly compressible carrier.
2. (originally presented) A pharmaceutical composition comprising:
 - i) a safe and therapeutically effective amount of (1*S*, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol or a pharmaceutically acceptable derivative thereof;
 - ii) a safe and therapeutically effective amount of (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof; and
 - iii) a pharmaceutically acceptable highly compressible carrier

wherein said composition has a volume in the range of 1.0 - 1.3 mL.

3. (originally presented) The present invention features a pharmaceutical composition in tablet form comprising:

- i) a safe and therapeutically effective amount of (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol or a pharmaceutically acceptable derivative thereof;
- ii) a safe and therapeutically effective amount of (2R,*cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one or a pharmaceutically acceptable derivative thereof; and
- iii) a pharmaceutically acceptable highly compressible carrier

wherein said composition exhibits a tablet hardness of greater than 18 kilopounds at 25 kilonewtons of force.

4. (currently amended) A pharmaceutical composition according to ~~any of Claims 1-3, claim 2~~ wherein the pharmaceutically acceptable highly compressible carrier is selected from a group consisting of diluents, binders, and fillers.
5. (originally presented) A pharmaceutical composition according to Claim 4 wherein the pharmaceutically acceptable highly compressible binder is selected from the group consisting of highly compressible microcrystalline cellulose.
6. (originally presented) A pharmaceutical composition according to Claim 5 wherein the compressible microcrystalline cellulose is Ceolus® microcrystalline cellulose.
7. (currently amended) A pharmaceutical composition according to ~~any of claims 1-3- claim 2~~ comprising (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol, or a pharmaceutically acceptable derivative thereof, (2R,*cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one, or a pharmaceutically acceptable derivative thereof, wherein said (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol and (2R,*cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one are present in an amount of 20% to 80% of total composition weight.
8. (currently amended) A pharmaceutical composition according to ~~any of Claims 1-7 claim 2~~ wherein the amount of (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-

purin-9-yl]-2-cyclopentene-1-methanol is from about 15 to about 1200 mg per unit dosage form.

9. (currently amended) A pharmaceutical composition according to ~~any one of Claims 1—7~~ claim 2 wherein the amount of (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one is from about 15 to about 1500 mg per unit dosage form.

10. (originally presented) A pharmaceutical composition according to Claim 9 wherein the amount of (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one is from about 100 to about 500 mg per unit dosage form.

11. (originally presented) A pharmaceutical composition according to Claim 10 wherein the amount of (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one is 300 mg per unit dosage form.

12. (currently amended) The pharmaceutical composition according to ~~any of Claims 1—11~~ claim 2 wherein (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one is provided substantially free of the corresponding (+)-enantiomer.

13. (currently amended) The pharmaceutical composition according to ~~any of Claims 1—11~~ claim 2 wherein (2*R,cis*)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1*H*)-pyrimidin-2-one is provided such that the corresponding (+)-enantiomer is present in an amount of not more than about 5% w/w of the amount of lamivudine.

14. (currently amended) The pharmaceutical composition according to ~~any of Claims 1—8~~ claim 2 wherein the pharmaceutically acceptable derivative of (1*S, cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol is the hemisulfate salt.

15. (currently amended) The pharmaceutical composition according to ~~any of Claims 1—6~~ claim 2 wherein the pharmaceutically acceptable highly compressible carrier is present in an amount of 5% to about 50% by weight.

16. (originally presented) A pharmaceutical composition comprising (1*S, cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol, or a

pharmaceutically acceptable derivative thereof, (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one, and Ceolus[®] microcrystalline cellulose.

17. (originally presented) A pharmaceutical composition consisting essentially of (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol, or a pharmaceutically acceptable derivative thereof, (2R,cis)-4-amino-1-(2-hydroxymethyl-1,3-oxathiolan-5-yl)-(1H)-pyrimidin-2-one, and Ceolus[®] microcrystalline cellulose.

18. (currently amended) A pharmaceutical composition according to ~~Claims 16 or 17~~ ~~claim 17~~ wherein the pharmaceutically acceptable derivative of (1S, *cis*)-4-[2-amino-6-(cyclopropylamino)-9*H*-purin-9-yl]-2-cyclopentene-1-methanol is the hemisulfate salt.

19. (currently amended) A pharmaceutical composition according to ~~any of Claims 3 - 18~~ ~~claim 17~~ wherein the composition has a has a volume in the range of 1.0 - 1.3 mL.

20. (currently amended) A pharmaceutical composition according to ~~any of Claims 1 - 19~~ ~~claim 2~~ in the form of a tablet.

21. (currently amended) A pharmaceutical composition according to ~~any of Claims 1 - 20~~ ~~claim 2~~ for once daily administration.

22. (currently amended) A pharmaceutical composition according to ~~any one of Claims 1 to 20~~ ~~claim 20~~ wherein the composition is coated with a pharmaceutically acceptable coating.

23. cancelled

24. cancelled

25. (currently amended) A method for treating, reversing, reducing or inhibiting retroviral infections by administering a safe and effective amount of a composition according to ~~any of Claims 1 - 21~~ ~~claim 2~~.

26. (originally presented) The method for treating, reversing, reducing or inhibiting retroviral infections according to Claim 25, wherein the retrovirus is HIV.

27. cancelled

28. cancelled

29. cancelled.

30. cancelled

31. cancelled